

Attorney Docket No.: KBI-0003
Inventors: Ranganathan and Dickstein
Serial No.: 09/557,011
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and distinctly claim the subject matter which the Applicants regard as the invention.

The Examiner suggests that the term "gut clearance rate" in claim 1 is indefinite. It is further suggested that the claim 1 phrase whereby the sorbents possess a gut clearance rate for urea of at least 5.6 ml./min. is indefinite. Applicants respectfully disagree.

Applicants believe that one skilled in the art would understand the term "gut clearance rate" to be a definite term of art. Further, Applicants believe that a mixture of sorbents which possess a gut clearance rate for urea of at least 5.6 ml/min. would be easily discernable based upon the disclosure of the invention. However, in an earnest effort to facilitate prosecution in this case, claim 1 has been further amended to clarify and distinguish the present invention. Specifically, it is recited that the mixture of sorbents of the present invention is both microencapsulated and enteric coated as supported throughout the specification and at page 9, lines 20-25, and that the mixture of sorbents comprises oxystarch, locust bean gum, and activated charcoal; as supported throughout the specification and at page 8, lines 9-14 The objected to phrase "wherein the sorbents possess a

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gut clearance rate for urea of at least 5.6 ml/minute" has been removed in an earnest effort to advance the prosecution.

The Examiner has further suggested that claim 1 fails to provide a material embodiment which would be more likely than not to function in the manner disclosed, and further that the specification does not support the breadth of the claims.

As recited in the MPEP §2164.08, not everything needed to practice the invention need be disclosed, in fact what is well-known is best omitted. *In re Buchner*, 929 F2d 660, 661, 18 USPQ2d 1331, 1332 (Fed Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See e.g. *In re Fisher*, 427 F.2d, 833 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F2d 1232, 169 USPQ 236, 239 (CCPA 1971).

As set forth previously, in an earnest effort to advance prosecution and clarify the invention, claim 1 has been amended to recite a microencapsulated and enteric coated mixture of sorbents

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with specific adsorption affinities for uremic toxins wherein the mixture of sorbents comprises oxystarch, locust bean gum, and activated charcoal as supported throughout the specification and particularly at page 8, lines 5-15. The claims as amended clearly satisfy the scope of enablement requirements under MPEP § 2164.08, and thus meet the requirements of 35 U.S.C. § 112, first paragraph. Accordingly, claim 1 is commensurate in scope with the disclosure, as the specification and claims allow one skilled in the art to practice the present invention.

Reconsideration and withdrawal of this rejection under 35 U.S.C. §112 is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

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Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made".

Respectfully submitted,

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Version with Markings to Show Changes Made

In the claims:

Please cancel claims 5-7.

Please amend claim 1 as follows:

1. (Amended) A microencapsulated and enteric coated composition comprising:

(a) a microencapsulated and enteric coated mixture of sorbents with specific adsorption affinities for uremic toxins ~~wherein the sorbents possess a gut clearance rate for urea of at least 5.6 ml/minute~~, wherein the mixture of sorbents comprises oxystarch, locust bean gum, and activated charcoal; and

(b) a bacterial source which metabolizes urea and ammonia.